
UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

United States of America, *et al.*,
ex rel.
Michael Vaughn, et al.,

Plaintiffs,

versus

United Biologics, LLC, *et al.*,

Defendants.

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Civil Action H-13-1081

**UAS'S MOTION FOR SUMMARY JUDGMENT ON
ALL OF RELATORS' CLAIMS**

TO THE HONORABLE JUDGE LYNN N. HUGHES:

Defendant United Biologics, LLC, d/b/a United Allergy Services (UAS) files this motion for summary judgment on all of relators' claims and for a declaration from the Court that UAS's percentage-based contracts do not violate the law.

The relators in this case allege UAS and physicians in contract with UAS have violated the False Claims Act and several analogue state statutes. These claims are premised on unsupported violations of the federal Anti-Kickback Statue and other technical issues relators raise concerning the medical and billing practices of physicians who contracted with UAS.

Because there is nothing unlawful about the agreements between UAS and its contracting physicians, and relators' various technical complaints concerning medical and billing practices do not rise to the level of False Claims Act violations, UAS seeks summary judgment on all claims relators have asserted in this suit and for a declaration that UAS's contracts do not violate the Anti-Kickback Statute or the federal or state false claims acts alleged by relators.

The legal authorities for UAS' motion are discussed in the attached brief in support of its motion for summary judgment.

Dated: October 25, 2016

Respectfully submitted,

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I hereby certify that on October 25, 2016, the foregoing document was served on the following individuals via the Court's e-filing system.

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SOUTHERN DISTRICT OF TEXAS

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**UAS’S BRIEF IN SUPPORT OF ITS MOTION
FOR SUMMARY JUDGMENT ON ALL OF RELATORS’ CLAIMS**

TO THE HONORABLE JUDGE LYNN N. HUGHES:

Vaughn seeks millions of dollars from UAS based on alleged violations of the False Claims Act and several analogue state statutes. In support, Vaughn alleges violations of the Anti-Kickback Statute and other technical issues that do not rise to the level of false claims. There is no contested issue of any material fact as it pertains to these allegations. Even if accepted as true, Vaughn's allegations constitute questions of law for the Court.

Vaughn's allegations primarily hinge on an assertion that by contractually agreeing to pay UAS a percentage of funds for allergy services billed to the government, the physicians somehow agreed to receive kickbacks for referral of patients to UAS. But there is nothing unlawful about the agreements between UAS and its contracting physicians, and Vaughn's various technical complaints concerning the practices of UAS or its contracting physicians do not rise to the level of False Claims Act violations. Thus, UAS seeks summary judgment on all claims Vaughn has asserted and for a declaration that UAS's contracts do not violate the Anti-Kickback Statute or the federal or state false claims acts Vaughn asserts.

FACTUAL BACKGROUND

UAS supplies allergy support services to physicians to assist those physicians in providing allergy skin prick testing and immunotherapy to the physician's patients. Ex. A (Declaration of Tom Thill) ¶ 3. UAS provides these services and the associated antigens and equipment as part of an agreement negotiated at arms-length. *Id.* ¶ 4; Ex. A-1 (Exemplary Contract). The physicians agree to provide the necessary professional medical services, including patient examination, medical history review, medical determinations, and supervision of UAS technicians. Ex. A-1 ¶ 2(a)-(e).¹ The amount and manner that a particular physician or clinic pays UAS for the services UAS provides varies depending on the contract. For example, a clinic or physician may agree to pay UAS a flat fee per service UAS performs, a flat monthly fee for these services, or an amount tied to the collections the clinic or physician receives for allergy services related to UAS's services. Ex. A ¶ 6.

Vaughn's allegations concern a contractual arrangement UAS primarily used from 2009 to 2012 in which the physician agreed to pay UAS a certain percentage of gross collections the physician received from insurance

¹ UAS submitted a copy of this same exemplary contract in the form requested by the Court, containing blue lines in the right margin indicating the relevant provisions. [Dkt. No. 80 at Ex. A.]

companies or the government for allergy services provided and billed by the physician. While Vaughn's allegations lack specifics, for purposes of this motion, an assumption may be made that certain physicians paid UAS either 60 or 70% of the gross collections those physicians received for claims they submitted to Medicare and Medicaid entities for allergy testing and immunotherapy services they provided to their patients. The fixed percentage varies between contracts. None of the contracts vary the amount of percentage paid based on the volume or amount of services performed by UAS or performed or billed by the contracting clinic or physician. Ex. A ¶ 7.

Vaughn filed this suit claiming UAS's percentage-based contracts were fraudulent under the Anti-Kickback statute and thus supported claims under the federal and state false claims acts. [Dkt. No. 7 ¶¶ 28, 29.] Vaughn also alleges that certain medical practices such as the method of "skin test grading" and dilution and delivery of immunotherapy led to inappropriate treatment and billing for those services. [*Id.* ¶¶ 30-40.]

ARGUMENT

The crux of Vaughn's lawsuit is that UAS's percentage-based contracts violate the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) and thus support claims under the False Claims Act and related state statutes. To prove a

violation of the Anti-Kickback Statute, Vaughn must show that UAS or the physicians involved paid unlawful remuneration to induce a referral of a patient under a federal health care program, and the conduct was done “knowingly and willfully” in violation of the law. 42 U.S.C. § 1320a-7b(b)(2)(A)-(B).

Vaughn cannot carry this burden for multiple independent reasons including: (1) there is no kickback paid by UAS to physicians; (2) the contractual payments from physicians to UAS reflect fair market value, not unlawful remuneration; and (3) UAS did not knowingly and willfully violate the law. Further, any of Vaughn’s other allegations against UAS or the contracting physicians do not rise to a level of fraud and were not material to the government’s decision to pay the alleged false claims. Vaughn’s claims should be dismissed.

1. No Kickback

Vaughn claims UAS and the physicians with whom UAS contracts violate the Anti-Kickback Statute, but Vaughn cannot identify any kickback. The undisputed evidence shows that the government pays the physician for claims he submits for allergy testing or immunotherapy services he performed for Medicare and Medicaid patients. The physician in turn pays UAS for the

antigens, equipment, and technicians UAS supplies to the physician to help perform those services. The payment flows from the physician to UAS for services UAS provided to the physician, and not in exchange for the referral of any patient. *See* Ex. A-1. There simply is no “kickback” in this payment structure as the money flows the wrong way.

While ambiguous in his complaint, Vaughn appears to claim that UAS “pays” the physician a kickback equaling the percentage of government funds the physician retains after paying UAS for its services. Vaughn’s odd “reverse payment” theory is a technical legal argument the government advanced and lost over 20 years ago. *See Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). In *Hanlester*, Smithkline BioSciences Laboratories (SKBL) contractually agreed with Hanlester’s network of physicians “to provide laboratory management services to all joint venture laboratories in which Hanlester had an ownership interest.” *Id.* at 1394. As part of that agreement, Hanlester billed the government and “agreed to pay SKBL a fee of 76 percent of the laboratories’ net revenues.” The government challenged this arrangement as a “kickback,” asserting SKBL was effectively paying Hanlester the “24 percent of net revenues” Hanlester retained from the government. *Id.* at 1401. The United States Court of Appeals for the Ninth Circuit disagreed.

That court observed that “[t]he management services agreement between SKBL and [Hanlester] reflects a relatively common practice in the clinical laboratory field.” *Id.* The percentage Hanlester retained from the government funds after paying SKBL was not a “kickback,” because the money flowed the wrong way:

The evidence shows that no payments were made to [the Hanlester entities], and that payments actually flowed from [the Hanlester entities] to SKBL in the form of fees for its management services.

The [Inspector General] did not prove that any of the appellants intentionally solicited or received remuneration from SKBL in return for referrals.

Id. Just as in *Hanlester*, the physician or his medical practice pays UAS a percentage of fees he receives from the government, not vice versa. There simply is no kickback.

Nor is there any basis for UAS or the physicians to conclude that any portion of the money paid by the government to the physician qualifies as a kickback. See *United States v. Alan Mackenzie, et al.*, CR-01-10350-DPPW (D Mass. 2004). As the federal district court in Massachusetts explained in instructing the jury in *Mackenzie*:

You will understand that payment from the federal health care program is not itself remuneration within the meaning of the anti-kickback statute. That would be circular. Of course a provider of medical services or goods

can be paid for drugs and related services if they are proper for payment under a federal health care program. And so I instruct you as a matter of law that any monies paid by the Medicare program or Medicaid program to physicians as reimbursement for Lupron or Prevacid do not constitute remuneration offered or paid indirectly by [defendant's employer] or any of the defendants before you.

Ex. C-1 (excerpt from jury instruction transcript).

In UAS's business model, the only payment the physician receives is from the federal health care program, not from UAS. Under Vaughn's bizarre theory, the only way the physician could avoid receiving a kickback would be to pay out all of that money to UAS or others who contribute to the service and retain nothing for his own services. The law rightfully does not require such an absurd result.

2. Payments are Fair Market Value for Services UAS Provides to the Physician

Another hurdle that Vaughn cannot meet is any proof that any alleged "kickback," whether from UAS to the physician or vice versa, could be considered anything other than fair market value for services UAS provides to the physician. If the physician pays UAS the fair market value of the services UAS contributes, that contractual exchange should not be considered improper remuneration. *See United States v. McKesson Corp.*, 900 F. Supp. 2d 683, 699 (N.D. Miss. 2012).

Whether a payment is fair market value rather than unlawful remuneration is “economics 101.” Fair market value is defined as “[t]he price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arms’-length transaction.” *See id.* (citing Black’s Law Dictionary (8th ed. 2005)); *Klaczak v. Consolidated Med. Transport*, 458 F. Supp. 2d 622, 679 (N.D. Ill. 2006)). The undisputed evidence proves that each of the agreements between the physicians and UAS that provide for payment for UAS’s services was negotiated and voluntarily executed at arms-length, without compulsion. *See* Ex. A ¶ 4. The physicians voluntarily agree to contract with UAS to provide additional services to their patients. Absent compulsion on the physician’s part or some other mechanism for UAS to pay the physicians, the contractually negotiated amount the physician pays UAS cannot provide unlawful remuneration.

3. No Knowing and Willful Intent to Violate the Law

Even assuming Vaughn could prove a kickback, he could never prove that UAS “knowingly and willfully” engaged in a kickback violation. To carry this burden, Vaughn must prove that the physicians and UAS acted with the intent to disobey or disregard the law. *See United States v. McClatchey*, 217 F.3d

823, 829-30 (10th Cir. 2000); *United States v. Stark*, 157 F.3d 833, 837–40 (11th Cir. 1998). But the undisputed facts conclusively prove the opposite.

UAS entered into these agreements with the understanding that they were commonplace in the industry. *See* Ex. A ¶ 8; *cf.* 42 C.F.R. § 411.354(d)(1) (expressly permitting percentage based compensation). The Office of Inspector General later issued an advisory opinion in November 2011 expressing concern about a particular percentage based arrangement of an anonymous entity.² In response, UAS sought and received a legal opinion from outside counsel regarding the OIG advisory opinion for the purpose of sharing the legal opinion with primary care doctors with whom UAS contracts. *See id.* Ex. A ¶ 9; Ex. B at ¶ 4; Ex. B-1 at 14 & n. 6, 7.³

² Vaughn asserts in an earlier filing that the sample contract UAS provided “appears to have been drafted after Defendant received the information in OIG Advisory Opinion No. 11-17” and thus is a “sham.” [Dkt. No. 87 at 1]. Vaughn knows this is untrue. The attached Exhibit A-1, which counsel supplied to Vaughn for redlining, is clearly dated October 28, 2011, while the OIG opinion was issued November 16, 2011.

³ Competitors, including relators have attempted to imply that OIG Advisory Opinion 11-17 applies to UAS. [Dkt. No. 87.] But in fact, the opinion was requested by a sham entity named “Universal Allergy Labs, LLC” for the purpose of obtaining a negative opinion and circulated anonymously to harm UAS. *See* Ex. A ¶ 9. Because UAS did not request the opinion, it does not apply to UAS and by its own terms is inadmissible in this Court. [Dkt. No. 87-1 at 6-7.]

The outside legal counsel, Kevin McAnaney, had previously worked as the former Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General and had written OIG advisory opinions. *See* Ex. A ¶ 9; Ex. B ¶¶ 2 & 4. Mr. McAnaney reviewed the agreements in December 2011 and confirmed what UAS already understood—the contractual arrangement between UAS and physicians did not provide for a kickback. *See* Ex. B. ¶¶ 3-5; Ex. B-1. In relying on Mr. McAnaney’s legal opinion, whether correct or not, UAS could not have intentionally and knowingly violated the law. *See United States v. Pollmann*, 364 F. Supp. 995, 1004 (D. Mont. 1973); *United States v. Interstate Eng’g*, 288 F. Supp. 402, 416 (D.N.H. 1967).

4. General Allegations Concerning Medicine are Immaterial

Finally, Vaughn alleges in his complaint various medical arguments why he believes the services competitor physicians provide is substandard or causes inappropriate treatment. [Dkt. No 7 at ¶¶ 30-40.] But the purpose of the False Claims Act is not to call into question a health care provider’s judgment regarding a specific course of treatment. *See, e.g., United States ex rel. Bailey v. Ector County Hosp.*, 386 F. Supp. 2d 759, 766 (W.D. Tex. 2004). To prove a claim under the False Claims Act, Vaughn must prove that UAS caused physicians to submit false or fraudulent claims or records to the

government that UAS knew were false or fraudulent. 31 U.S.C. § 3729(a)(1)(A)-(G). The negligent deficiencies Vaughn suggests in either the claims or underlying medical records or procedures are not enough.

Further, Vaughn must prove that the alleged misrepresentation or fraud underlying the claim was material to the government's decision to pay the claim. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003, 195 L. Ed. 2d 348 (2016). As the United States Supreme Court recently explained in construing the False Claims Act, “[t]he materiality standard is demanding” because the Act is not “an all-purpose antifraud statute.” *Id.*

Vaughn's suit prompted a 3 ½ year investigation by the government into the activities Vaughn claimed were false or fraudulent. That investigation resulted in non-intervention by the government in this case, no action requiring UAS or the physicians to change these disputed practices, and continued and uninterrupted payment of claims by primary care doctors for services rendered in part by UAS. *See* Ex. A ¶ 11. “If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not

material.” *See Universal Health Servs.*, 136 S. Ct. at 2003. Vaughn has no evidence to the contrary.

5. Vaughn’s State Law Claims Fail For The Same Reasons

Vaughn asserts claims under thirteen state statutes, each of which is modeled after the False Claims Act. [Dkt. No. 7, Counts 3-15, ¶¶ 122-147.] For the same reasons Vaughn cannot prove a violation of the False Claims Act, he cannot prove a violation of the various state acts. *See, e.g., United States ex rel. Kroening v. Forest Pharm., Inc.*, 155 F. Supp. 3d 882, 895 (E.D. Wis. 2016) (dismissing 29 counts alleging a claim under a state version of the FCA because “each state law is construed consistent with the FCA and thus each claim fails for the same reason [relator’s] FCA claims fail”); *United States ex rel. King v. Solway, S.A.*, No. H-06-2662, 2015 WL 8480148, at *3 (S.D. Tex. Dec. 10, 2015) (granting summary judgment holding no relevant difference between federal and Texas Anti-Kickback Statutes); *Cade v. Progressive Cmty. Healthcare, Inc.*, No. 1:09-cv-3522, 2011 WL 2837648, at *3 (N.D. Ga. July 14, 2011) (dismissing False Claims Act and Georgia False Medicaid Claims Act, which “uses nearly identical language”).

PRAYER

UAS prays that the Court grant summary judgment dismissing on the merits all claims asserted by Vaughn in this case and declaring that United Allergy Services' percentage-based contracts do not violate the anti-kickback statute or federal or state false claims acts as Vaughn has alleged.

Dated: October 25, 2016

Respectfully submitted,

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UNITED STATES DISTRICT COURT

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Civil Action H-13-1081

**[PROPOSED] ORDER GRANTING SUMMARY JUDGMENT
ON ALL OF RELATORS' CLAIMS**

The Court has considered United Allergy Services' motion for summary judgment. After considering the issues, the Court finds that summary judgment is appropriate on all of Relators' claims. The Court concludes that United Allergy Services' percentage-based contracts do not violate the anti-kickback statute or federal or state false claims acts as Vaughn has alleged. Relators' false claims act claims on behalf of the United States government and the various states are dismissed with prejudice.

Signed _____, 2016.

Lynn N. Hughes
United States District Judge